

REMARKS

The amendment to the specification, claiming priority, is proper without the filing of a petition under 37 C.F.R. § 1.78(a)(3) because the present application, which was filed on November 25, 2000, is an "application filed under 35 U.S.C. 111(a) before November 29, 2000" [37 C.F.R. § 1.78(a)(2)(ii)(B)], such that the time periods recited in 37 C.F.R. § 1.78(a)(2)(ii) do not apply.

The amendments to the claims do not add new matter. Claim 45 has been amended to recite that the polygonal spinal spacer has an "anterior end" and a "posterior end." Support for the polygonal spinal spacer having an "anterior end" and a "posterior end" is found throughout the specification, including at page 9, lines 12-15 ("Alternatively, the implant is passed several times over a ridged surface which cuts the desired tooth profile into the upper, lower, or both surfaces of the implant. Preferably, the thus formed teeth angle toward the anterior (convexly curved) face of the implant to prevent backing out of the implant once it is inserted into an appropriately shaped cavity formed in the intervertebral space in an anterior aspect of the cervical spine," and at Fig. 12A, superimposing the relative size and shape of the polygonal shaped implant over the D-shaped implant having the "anterior (convexly curved) face." Like Fig 12A, Figs 13A-17A superimpose the size and shape of the polygonal shaped implant over the D-shaped implant having the "anterior (convexly curved) face." The recitation in claim 45 to "rows of migration resistant projections, ribbing or teeth angling toward the anterior end of said spacer to prevent said spacer from backing out from between said vertebrae," is supported by the above cited recitation in the specification at page 9, lines 12-15, and by Fig. 12B (and 13B, 14B, 15B, 16B and 17B), showing the rows of projections (or teeth) being directed toward the anterior end of the implant.

The amendment to claims 46-51, which recites that the spacer is in "assembled form," is supported throughout the specification, wherein the implants is disclosed as being made from several components stacked or in juxtaposition to one another and held together with pins or a bone plug acting as a pin. Specifically, support for the assembled form is found in the specification at page 17, lines 27 to page 18, line 3 ("In a further embodiment of this invention, shown in FIG. 8, a method for **assembling** the

implant of this invention from component parts is provided. In FIG. 8A, there is shown an implant 800 composed of two side-by-side halves, 801A and 801B. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other.”); at page 17, lines 4-6 (“According to this embodiment of the invention, **two implant blanks** of known height are selected such that a **unitary implant** composed of both starting implants can be **produced** of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant”); at page 17, lines 8-11 (“**Pins**, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then **impelled** into the holes in the implants such that the implants are **formed into a unitary body by these pins**); at page 17, lines 13-15 (“In FIG. 7B, there is shown the **juxtaposition of two implants** 700A and 700B, with the drilled holes 701-704 in register to **receive pins for maintaining the implants in register**”); and at page 17, lines 21-22 (“By press-fitting the two implants together using an appropriately shaped cancellous plug 905. . .”).

Claims 47 and 48, which recite that the components of the spacer are “stacked” or in “juxtaposition,” are supported throughout the specification, including the citations in the preceding paragraph, such as at page 16, line 30 (“stacking”); page 17, lines 6 (:stacked”); and page 17, lines 13, 25 and 30 (“juxtaposition”).

Claim 49, which recites that the “internal” canal has a shaped cancellous bone portion therein, is supported throughout the specification, including at page 6, line 15 (“internal canal”); at page 7, line 1 (“internal canal”); at page 7, line 4 (“any desired final shape for the canal”); at page 7, lines 17-18 (“Having formed an asymmetric shape, such as a key way, from the internal canal running through the implant. . .”); and at page 17, lines 21-26 (“By press-fitting the two implants together using an appropriately **shaped cancellous plug** 905 . . . the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.”).

Claim 52, which recites that the “rows of migration resistant projections, ribbing or teeth have a flat end.,” is supported throughout the specification, including at Figs. 6E, 6F, 6G, 6H, 6I, 7B, 12C, 13C, 14C, 15C, 16C and 17C.

Claim 53, which is directed to the spacer of claim 45 wherein the “rows of migration resistant projections, ribbing or teeth occur on said superior vertebral engaging surface,” is supported throughout the specification, including at page 9, lines 4-9 (“substantially "D"-shaped cortical bone implant with flat upper and lower surfaces, or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the implant.”).

Claim 54, which is directed to the spacer of claim 45 wherein the “rows of migration resistant projections, ribbing or teeth occur on said inferior vertebral engaging surface,” is supported throughout the specification, including at page 9, lines 4-9 (“substantially "D"-shaped cortical bone implant with flat upper and lower surfaces, or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the implant.”).

Claim 55, which is directed to the spacer of claim 54 wherein the “rows of migration resistant projections, ribbing or teeth occur on said superior vertebral engaging surface,” is supported throughout the specification, including at page 9, lines 4-9 (“substantially "D"-shaped cortical bone implant with flat upper and lower surfaces, or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the implant.”).

Claim 56, which is directed to the spacer of claim 52 having a “diamond-shaped external profile,” is supported throughout the specification, including at page 20, lines 27-28 (“As can be seen, the implant produced according to this aspect of the invention has a substantially diamond-shaped external profile . . .”).

Claim 57, which is directed to the spacer of claim 52, wherein the shaped internal canal is "circular," is supported throughout the specification, including at page 6, lines 15-17 ("the circular internal canal formed by the centrally located solid drill bit of the core-cutter is modified to form an asymmetric shape, such as a key way.").

Claim 58, which is directed to the spacer of claim 52, wherein the shaped internal canal is "D-shaped," is supported throughout the specification, including at page 6, lines 19-21 ("we have found that an implant of consistently good final quality may be machined by conversion of the circular canal into a substantially "D" shaped canal . . .").

Claim 59, which is directed to the spacer of claim 52, wherein the shaped internal canal is "asymmetric," is supported throughout the specification, including at page 6, lines 15-17 ("the circular internal canal formed by the centrally located solid drill bit of the core-cutter is modified to form an asymmetric shape, such as a key way.").

Claim 60, which is directed to the spacer of claim 45, wherein said anterior end has "unbeveled edges," is supported throughout the specification, including at page 9, lines 18-19 ("but leaving the anterior face unbeveled.").

Claim 61, which is directed to the spacer of claim 45, wherein said anterior end has a "sharp" edge to "retard backing out of the implant," is supported throughout the specification, including at page 9, lines 19-20 ("The sharp anterior edge, like the teeth in the upper and lower surfaces of the implant, retards backing out of the implant.").

Claim 62, which is directed to the spacer of claim 61, wherein said posterior end has a "beveled edge of defined radius," is supported throughout the specification, including at page 9, lines 18-19 ("a beveled edge of defined radius is preferably machined into three faces of the implant, but leaving the anterior face unbeveled.").

Claims 63 and 64 parallel claims 61 and 52, respectively, and are supported by the corresponding disclosures as cited above.

For all these reasons, the amendments to the specification and claims do not add new matter.

Bases for Objection/Rejection

The Patent Office alleges that the Applicants claim of priority is incorrectly claimed from an abandoned application.

Claim 46 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claim 48 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

The Drawings are objected to because they allegedly fail to show claims 47-48.

Claims 45-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,258,125 (Paul).

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford).

Claims 45-46, and 48-49 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,033,438 (Bianchi).

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre).

Each of these bases for rejection and/or objection will be addressed in Sections I-IX, respectively, which follow.

I. Claim of Priority

The Patent Office alleges that the Applicants' claim of priority is incorrectly claimed from an abandoned application. Specifically, the Patent Office contends that "[t]his applicant incorrectly claims continuation in part (CIP) to 08/920,630, filed 08/27/97," whereas "08/920,630 went abandoned on 04/18/01 which is prior to the filing date of 08/25/98 for the current application." [Official Action at page 2.] The Applicants respectfully disagree.

In the second preliminary amendment filed 04/10/03, the Applicants clarified their claim of priority by reflecting that the parent application, USSN 09/701,933, now pending, "is the national phase of PCT/US98/17769, filed 08/27/1998," which is the continuation-in-part of USSN 08/920,630, filed 09/27/1997, now abandoned. The Patent Office failed to address this amendment in the Official Action. Because the present application, having a filing date of 11/25/00, is "an application filed before November 29, 2000" [37 C.F.R. § 1.78(a)(2)(ii)(B)], the Applicants are not required to abide by the subsequently enacted time periods in 37 C.F.R. § 1.78(a)(2)(ii). Thus, when the Applicants priority claim is considered, as it must be, the Applicants' invention properly claims priority back to 08/27/1997. However, out of an abundance of caution, the Applicants have further amended their claim of priority in the present response to reflect that the "National Stage" application is a "371" National Stage application of PCT/US98/17769, filed 08/27/1998, which in turn is a "which is a continuation-in-part of USSN 08/920,630, filed 08/27/1997, now abandoned." For all these reasons, the present application is entitled to a claim of priority back to 08/27/1997.

II. 35 U.S.C. § 112, Second Paragraph

Claim 46 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the term "composite", as used in claim 48, is "ambiguous." [Official Action at page 2.] Specifically, the Patent Office contends that in the art, the term "composite" is usually a material limitation. [Official Action at page 2.] The Patent Office requests that the Applicants provide support and a definition in the specification. In response, the Applicants have amended the claims, to delete the noun "composite" and replace it with the adjective "assembled." Support for the claimed spacers being in "assembled" form is found throughout the specification both expressly and otherwise: at page 18, lines 27 to page 18, line 3 ("In a further embodiment of this invention, shown in FIG. 8, a method for **assembling** the implant of this invention from component parts is provided. In FIG. 8A, there is shown an implant 800 composed of two side-by-side halves, 801A and 801B. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition,

or holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other.”); at page 17, lines 4-6 (“According to this embodiment of the invention, **two implant blanks** of known height are selected such that a **unitary implant** composed of both starting implants can be **produced** of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant”); at page 17, lines 8-11 (“**Pins**, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then **impelled** into the holes in the implants such that the implants are **formed into a unitary body by these pins**); at page 17, lines 13-15 (“In FIG. 7B, there is shown the **juxtaposition of two implants** 700A and 700B, with the drilled holes 701-704 in register to **receive pins for maintaining the implants in register**”); and at page 17, lines 21-22 (“By press-fitting the two implants together using an appropriately shaped cancellous plug 905. . .”).

Thus, this basis for rejecting claim 46 under 35 U.S.C. § 112, second paragraph, has been rendered moot.

III. 35 U.S.C. § 112, First Paragraph (Enablement)

Claim 48 is rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. According to the Patent Office, the specification is “enabling for the species shown in figure 8A having two pieces juxtaposition to one another, does not reasonably provide enablement for the elected species shown in figure 12A.” [Official Action at page 3.] The Patent Office also states the same basis for rejection for claim 47, which claims “two stacked pieces.” [Official Action at page 3.] In addition, the Patent Office has objected to the drawing because they fail to show “two stacked pieces or two pieces in juxtaposition to one another as claimed.” [Official Action at page 3.] The Patent Office contends that “[a]ny structural detail that is necessary for understanding the invention should be shown in the drawing.” [Official Action at page 3, citing MPEP § 608.02(d).] Finally, the Patent Office contends that “[a] proposed drawing correction or corrected drawings are required in reply to the Office Action to avoid abandonment of the application.” [Official Action at page 3.]

In response, the Applicants respectfully submit that Figure 9 of the specification shows an intervertebral spacer comprising two stacked components 901 and 902. The Applicants respectfully submit that the word "stacked" is a common word that is used in its ordinary sense to mean an orderly pile:

stack 2. any somewhat orderly pile or heap, as of boxes, books, poker chips, etc.

[Exhibit A: Webster's New World Dictionary, Second College Edition, Prentice Hall Press, Cleveland OH, 1986 at page 1384.]

One skilled in the art, seeing Fig. 9 or contemplating a "stack" of pancakes would understand what is meant by the word "stacked" as used in claim 47. Further, in Fig 12A, the polygonal implant is shown superimposed over the same shaped implant as used in Fig. 9 such that one skilled in the art would be able to understand how to stack the implants of Fig. 12A, or any of the other similarly shaped implants of Figs. 12B-17D. However, in compliance with the Patent Office's request, the Applicants have amended Fig. 12 by adding Fig. 12E, paralleling Fig. 9 and showing the implant of Fig 12A in a stacked form over a second implant of 12A.

The Applicants' claims also use the word "juxtaposition." The Applicants respectfully submit that the ordinary word "juxtaposition" was used in its common and ordinary sense to mean to put side by side or close together:

juxtapose to put side by side or close together -- **juxtaposition**
n.

[Exhibit A: Webster's New World Dictionary, Second College Edition, Prentice Hall Press, Cleveland OH, 1986 at page 767.]

Because the word "juxtaposition" was used in its common and ordinary sense to mean "side by side" or "close together," it encompasses both "side by side" and "stacked," since the latter is "close together." Consistent with the Patent Office's suggestion, the Applicants enclose with their filing a substitute Fig. 12 of the specification (sheet 17/22), containing Fig. 12F (which is analogous to Fig. 8), showing the spacer of Fig. 12A comprising "two polygonal cortical bone portions in juxtaposition to one another." The specification discloses that the

stacked embodiments or the embodiments in juxtaposition are held together with “cortical bone pins” or a “cancellous plug” fitted into the inner canal:

FIG. 9 provides a view of a stacked embodiment of the implant of this invention wherein the **stacked constituents** thereof are retained in registered relationship by press-fitting or otherwise bringing more than one implant into contact with each other and having a **cancellous plug** or other biocompatible material located in the central **canal** of each stacked implant, thereby **acting as a retention pin**.

[Specification at page 3, lines 13-17; emphasis added in bold.]

* * *

Such **stacked** implants may be maintained in a unitary association by **drilling appropriate holes** through the height of the implant, and inserting therein appropriate **retention pins** made from any desirable material, including **cortical bone**, bioabsorbable synthetic polymer, titanium or other metallic retention pins. **Alternatively**, the **stacked** implants may be retained in a unitary association by means of a **plug of cancellous bone**, hydroxyapatite or other biocompatible, osteoconductive or osteoinductive material, and **press-fitting the stacked implants to achieve the desired height** (see FIG. 9).

[Specification at page 5, lines 18-24; emphasis added in bold.]

Thus, the specification, as originally filed, taught one skilled in the art how to make and use the various embodiments of spacer (implants) of the Applicants' invention.

In view of the arguments herein and the amendments to Fig. 12, as cofiled herewith, all bases for the rejection of claims 47 and 48 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement have been rebutted. The specification, as originally filed, was enabling.

IV. Objection to the Drawings

The Drawings are objected to because they allegedly fail to show the embodiments recited in claims 47-48. The Patent Office required that the Applicants provide proposed drawing corrections, showing these embodiments, to avoid abandonment. [Official

Action at page 3.] As discussed above, the Applicants have cofiled herewith a proposed substitute Fig. 12 (sheet 17/22), providing Figs. 12E and 12F depicting the stacked and juxtapositioned embodiments, respectively, which were already described in the specification. See Section III *supra*. In view of the proposed corrected drawings, as cofiled herewith, this basis for objection has been rendered moot.

V. Double Patenting

Claims 45-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over the claims of copending application 09/701,933. According to the Patent Office, the Applicants are claiming a "continuation" of 09/701,933. The Applicants have amended their claim of priority, in light of the restriction requirement that has been imposed, to reflect that the present application is a "division" of 09/701,933. Moreover, copending application, USSN 09/701,933, is claiming the embodiment of Figs. 8A-8C, which have been finally rejected and which the present Examiner has determined to be patentably distinct:

... the specification, while being enabling for the species shown in figure 8A having two pieces in juxtaposition to one another, does not reasonably provide enablement for the elected species shown in figure 12A.

[Official Action at page 3.]

* * *

This application contains claims directed to the following patentably distinct species of the claimed invention:

- I. Figures 1a-1b
- II. Figures 1c-1e
- III. Figures 6a-6c
- IV. Figures 6d-6f
- V. Figures 6g-6i
- VI. Figures 7a
- VII. Figures 8a
- VIII. Figures 8d-8g
- IX. Figures 12a-12d
- X. Figures 13a-13f

- XI. Figures 14a-14f
- XII. Figures 15a-15f
- XIII. Figures 16a-16f
- XIV. Figures 17a-17f

[Official Action of 01/14/03 at page 3-4.]

For all these reasons, the provisional rejection of claims 45-51 (and presumably newly submitted claims 52-62) is legally erroneous and should be withdrawn.

VI. 35 U.S.C. § 102(e) over Paul

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,258,125 (Paul). According to the Patent Office, Paul “teaches a polygonal cortical spinal spacer.” [Official Action at page 5, citing to Paul at Fig. 7 and Fig. 8, allegedly showing pieces in juxtaposition.] The Applicants respectfully disagree.

A. Paul is not § 102 Prior Art

In order to be prior art, Paul must at least have a claimed priority filing date that is prior to the priority filing date of the present application. In the present case, the Applicants have amended their claim of priority to correctly reflect a priority filing date of **08/27/1997**. In contrast, Paul has an earliest claimed priority filing date of **08/03/1998**. Thus, on its face, Paul was filed almost one year after the Applicants’ earliest claimed filing date.

In the present case, the Patent Office has implicitly admitted that the Applicants’ claims are entitled to the filing date **08/27/1997** of the grandparent application. The grandparent application was filed on **08/27/1997** with Figs. 1A-8C. The parent (PCT) and the present application were filed with the text of the grandparent application and added Figs. 8D-17a-f. On 01/14/2003, the Patent Office imposed a restriction requirement finding that “**no claim was generic**” and that the claims were “directed to the following patentably distinct species of the claimed invention:

- I. Figures 1a-1b
- II. Figures 1c-1e
- III. Figures 6a-6c

- IV. Figures 6d-6f
- V. Figures 6g-6i
- VI. Figures 7a
- VII. Figures 8a
- VIII. Figures 8d-8g
- IX. Figures 12a-12d
- X. Figures 13a-13f
- XI. Figures 14a-14f
- XII. Figures 15a-15f
- XIII. Figures 16a-16f
- XIV. Figures 17a-17f

[Official Action of 01/14/03 at page 3-4.]

The Applicants elected to pursue Group IX directed to Figs. 12a-12d. The Applicants also argued that their claims were generic. Notwithstanding the Patent Office's contention that the species are patentably distinct and would require a separate search, the Patent Office cited to Pafford as being anticipatory of Applicants' claims 45-51 for disclosing in Figures 29-42 D-shaped spacers that were "a similar embodiment to applicant's **figure 1** which is fully capable of being stacked or placed in juxtaposition." [Official Action at page 5; emphasis added in bold.] The Patent Office's admission has multi-fold implications. Implicit in the Patent Office's admission is that Applicants' current claims read on the embodiment in Applicants' Figure 1 because they are allegedly anticipated by the same D-shaped disclosures in Pafford which correspond to Applicants' Fig. 1. If the Applicants' claims are generic enough to read on the spacer of Fig. 1, then the Applicants' claims are entitled to the earliest claimed filing date of Fig. 1, which is **08/27/1997**. For this reason, Paul, which has a filing date of **08/03/1998** is not prior art.

Separately, the Patent Office has also stated that it "interprets **figures 29-42** [of Pafford] being 'substantially diamond shaped.'" [Official Action at page 5; emphasis added in bold.] These are the same figures that the Patent Office admitted a few sentences earlier "correspond to applicants' **figure 1** which is fully capable of being stacked or placed in juxtaposition." [Official Action at page 5; emphasis added in bold.] Thus, even the Applicants' dependent claims, such as claims 50 and 56, which read on a spacer that is "substantially diamond shaped" would be entitled to the Applicants' claimed priority filing date of **08/27/1997** because they allegedly read on the same D-shaped implants as figures 29-

42 of Pafford that the Patent Office already admitted are “a similar embodiment to applicant’s figure 1” [which is clearly entitled to the claimed priority filing date of **08/27/1997**]. For these reasons, dependent claims 50 and 56 are entitled to the priority filing date of **08/27/1997** such that Paul is not prior art.

B. Even if Paul is Prior Art, Paul is Not Anticipatory

Assuming *arguendo* that Paul is prior art, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros. v. Union Oil.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In the present case, independent claim 45 recites as an element that the spacer “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer** to prevent said spacer from backing out from between said vertebrae.” [Emphasis added in bold.] This is shown in Fig. 1D of the Applicants’ invention and is described in the specification at page 10, line 7 (“a set of teeth, all of which angle toward the anterior face 108 of the implant.”). In contrast, Paul teaches the use of teeth that are either “pyramid-shaped” [Paul at col. 3, lines 41-42] and thus symmetrical; or having a “saw-tooth shape with the saw tooth **running in the anterior-posterior direction.**” [Paul at col. 3, lines 43-45; emphasis added in bold.] Referring to Figure 9 of Paul, the rows of teeth at the anterior side 26 [Paul at col. 4, lines 9-10 (“from an anterior side 26 to a posterior side 28”)] of the implant are shown as **angling toward the posterior end 28**. Consistent with Fig. 9 and Paul’s written disclosure, the spacer in Fig. 11 of Paul also shows the teeth 12 angling from the anterior end 26 toward the posterior end 28. Because Applicants’ claim 45 recites that the rows of teeth “angle toward the **anterior end**,” whereas Paul teaches teeth which angle toward the **posterior end**, Paul would not be anticipatory of claim 45 of the Applicants’ invention. Because claims 46-64 of Applicants’ invention are dependent upon claim 45, they incorporate by reference the element that the teeth “angle toward the anterior end.” Accordingly, claims 46-64 would not be anticipated by Paul.

For all these reasons, any rejection of claims 45-64 over Paul would be legally and factually erroneous.

VII. 35 U.S.C. § 102(e) over Pafford

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford). According to the Patent Office, Pafford discloses “numerous embodiments of [a] polygonal cortical spinal spacer.” [Official Action at page 5.] The Patent Office further contends that “figures 29-42 [of Pafford] teach[] a similar embodiment to applicant’s figure 1 which is fully capable of being stacked or placed juxtaposition (see also figure 24 for juxtaposition).” [Official Action at page 5.] Finally, the Patent Office cites to figures 39 and 40 for “teaching migration resistant projections” and “interprets **figures 29-42** [of Pafford] being ‘substantially diamond shaped.’” [Official Action at page 5; emphasis added in bold.] The Applicants respectfully submit that Pafford is not anticipatory of claims 45-51 or newly submitted claims 52-64.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros. v. Union Oil.*, 814 F.2d 628, 631 (Fed. Cir. 1987). In the present case, independent claim 45 recites as an element that the spacer “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer** to prevent said spacer from backing out from between said vertebrae.” [Emphasis added in bold.] This is shown in Fig. 1D of the Applicants’ invention and is described in the specification at page 10, line 7 (“a set of teeth, all of which angle toward the anterior face 108 of the implant.”). In contrast, the **only** alleged disclosures of rows of teeth in Pafford are at Figs. 39 and 40. [Official Action at page 5.] Fig.39 of Pafford discloses a “waffle . . . pattern” [Pafford at col. 13, line 9] wherein each indentation and ridge is symmetrical and not biased in any direction. Figure 40 discloses teeth that are symmetrical and not biased toward the anterior end. Accordingly, Pafford is not anticipatory of claim 45 or its dependents (claims 46-64) because Pafford fails to disclose any spacer that has an element “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer.**” The withdrawal of this basis for rejection is respectfully requested.

VIII. 35 U.S.C. § 102(e) over Bianchi

Claims 45-46, and 48-49 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,033,438 (Bianchi). According to the Patent Office, “Bianchi et al teach a polygonal cortical spinal spacer comprising two pieces capable of being placed in juxtaposition. See figure 9.” [Official Action at page 5.] The Applicants respectfully submit that Bianchi would not be anticipatory of the original claims or the claims as amended.

As an initial matter, the device shown in Bianchi is not a polygon. By definition, a polygon is a figure consisting of **straight lines joined end to end** and forming angles:

polygon -a closed figure consisting of **straight lines joined end to end**.

[Exhibit B: Webster’s Third New International Dictionary of the English Language Unabridged, Gove, Ed., Merriam-Webster Inc., Publishers, Springfield MA, 2002 at page 1758; emphasis added in bold.]

In contrast, the spacers in Bianchi are “dowels” [Bianchi at col. 1, lines 33-34 (“making a dowel according to this invention”)] which one skilled in the art recognizes as a cylinder and not as a polygon:

dowel - a peg or pin of wood, metal, etc. usually fitted into corresponding holes in two pieces to fasten them together.

[Exhibit A: Webster’s New World Dictionary, Second College Edition, Prentice Hall Press, Cleveland OH, 1986 at page 422; see also the figure showing a dowel as a “cylinder”.]

As evidence that those skilled in the art consider a “dowel” to be a cylinder, the Applicants rely upon McIntyre, which is cited by the Patent Office. McIntyre discloses in Figs. 1 and 2 as element 12, a “dowel body” [McIntyre at col. 2, line 59 (dowel body 12”)] which element McIntyre also describes as an “elongated substantially cylindrical cortical body member 12” [McIntyre at col 2, lines 30-31]. Because the spacers of the Applicants’ invention are **polygons** with angles, they **resist turning**. In contrast, the **dowels** of Bianchi are inherently cylindrical (lacking angles) and are threaded and **designed to turn**. For this reason, the

cylinder-based “dowel” spacers of Bianchi are not anticipatory of the “polygonal” spacers of the Applicants’ invention.

Separately, independent claim 45 (and dependent claims 46-64 by reference thereto) have been amended to recite that the claimed spacer comprises “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer.**” In contrast, the cylindrical dowels of Bianchi have “threads” [Bianchi at col. 7, line 54 (“machined threads”). By definition, a thread (singular) is not “rows” (plural), but rather a singular **spiral or helical ridge of a screw**:

thread - 4. the spiral or helical ridge of a screw, bolt, nut, etc.

[Exhibit A: Webster’s New World Dictionary, Second College Edition, Prentice Hall Press, Cleveland OH, 1986 at page 1481.]

Moreover, there is no disclosure in Bianchi of “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer.**” For all these reasons, claims 45-64 would not be anticipated by Bianchi.

IX. 35 U.S.C. § 102(e) over McIntyre

Claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre). McIntyre is cited for disclosing a “substantially diamond-like polygonal cortical spinal spacer.” [Official Action at page 6.] However, independent claim 45, and each of claims 46-64 which depend therefrom, recite as an element that the polygonal spacer comprise “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer.**” McIntyre fails to disclose any “rows of migration resistant projections, ribbing or teeth” and particularly not any “rows of migration resistant projections, ribbing or teeth **angling toward the anterior end of said spacer.**” For these reasons, McIntyre would not be anticipatory of claims 45-64 of the present application. The withdrawal of this basis for rejection is respectfully requested.

CONCLUSION

Claims 45-51 stand rejected. No claims have been cancelled. Claims 52-64 have been added. Accordingly, claims 45-64 are pending.

In view of the amendment and arguments herein, the Applicants have established that they are entitled to the priority date of 08/27/97.

In view of the amendment herein, the rejection of claim 46 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot.

In view of the amendment to Figure 12 herein, the rejection of claims 47-48 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement has been rendered moot.

In view of the amendment to Figure 12 herein, the objection to the drawings for allegedly failing to show claims 47-48, has been rendered moot.

In view of the arguments and amendment herein, the provisional rejection of claims 45-51 under the judicially created doctrine of obviousness-type double patenting has been rendered moot.

In view of the arguments and amendment herein, the rejection of claims 45-51 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,258,125 (Paul) has been rebutted and or rendered moot.

In view of the arguments and amendment herein, the rejection of claims 45-51 under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,371,988 (Pafford) has been rebutted and or rendered moot.

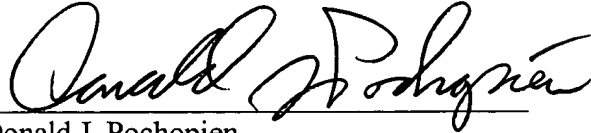
In view of the arguments and amendment herein, the rejection of claims 45-46, and 48-49 under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,033,438 (Bianchi) has been rebutted and or rendered moot.

In view of the arguments and amendment herein, the rejection of claims 45-51 under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 4,950,296 (McIntyre) has been rebutted and or rendered moot.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:

A handwritten signature in black ink, appearing to read "Donald J. Pochopien", written over a horizontal line.

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

Date: December 04, 2003

J:\open\Djp\Regeneration Technologies\USPTO\13971US03\13071US03 Response Under 1.111.doc